

U.S. DEPARTMENT OF DEFENSE
SMALLPOX VACCINATION PROGRAM
INFORMATION STATEMENT AND CONSENT

IMPORTANT INFORMATION ABOUT SMALLPOX VACCINE

Please read carefully!

What is Smallpox?

Smallpox is a very serious disease; it is contagious and sometimes fatal.

Smallpox is an infection caused by a germ called variola virus. About 3 out of 10 people infected with smallpox will die. Survivors are often scarred and, rarely, may be blinded.

Smallpox no longer occurs naturally on the earth. There is a danger that smallpox could be released as a bio-weapon. Smallpox spreads slowly, usually by face-to-face contact for an hour or more with a contagious person. People with smallpox become contagious just before a rash begins and just after their temperature goes over 101°F (38.3°C). They stay contagious until all their scabs fall off. Smallpox can be spread by contact with inanimate objects (such as clothing, towels, linens), but this would be uncommon.

The symptoms of smallpox begin with high fever, head and body aches, and sometimes vomiting. A rash follows that spreads and progresses to raised bumps that crust, scab, and fall off after about three weeks, leaving a pitted scar.

Smallpox can be prevented through the use of smallpox vaccine (discussed below).

What Is The Smallpox Vaccine?

Smallpox vaccine is named for the disease it prevents, not for the virus it contains. Smallpox vaccine contains live vaccinia virus to protect against smallpox infection. Smallpox infection is caused by a virus called variola virus. You cannot get smallpox (infection from variola virus) from a smallpox vaccination.

The same smallpox vaccine being offered to you was given to many millions of Americans throughout the 20th century, including millions of U.S. Service Members during World War I, World War II, and through the 1980s.

The Food & Drug Administration (FDA) recently licensed a limited supply of smallpox vaccine made by Wyeth Laboratories, called *Dryvax*®. Smallpox vaccine used by the Department of Defense passes all tests required by the FDA.

The World Health Organization (WHO) used smallpox vaccine to eradicate natural smallpox from the planet. After a single smallpox vaccination, about 95% of people develop protection within 10 days.

The benefit of smallpox vaccine to you could be very low or very high. Smallpox vaccination would have little value to you personally, if people contagious with smallpox never come near you or you are not exposed to smallpox as a bio-weapon. Smallpox vaccination could have great value to you personally, if you come near people contagious with smallpox or if you are exposed to smallpox as a bio-weapon, especially for the first 5 to 10 years after vaccination. Your acceptance of smallpox vaccination would help America's defenses against the potential use of smallpox as a bio-weapon. Being vaccinated against smallpox will enable you to continue in your assigned task or mission. For example: being part of a medical response team to examine, interview, or treat people possibly or actually infected, or to do other tasks to help contain a smallpox outbreak.

Most Americans born before 1972 were vaccinated against smallpox earlier in life. Most Americans born since 1972 have not been vaccinated against smallpox previously. People vaccinated against smallpox more than 10 years ago may have some partial immunity remaining, but need another smallpox vaccination to restore full immunity.

Who Should Be Vaccinated?

The likelihood of a smallpox outbreak is considered low. But if a smallpox outbreak occurs, America will need people vaccinated against smallpox to contain and stop the outbreak and to perform military critical mission-related tasks.

While the Department has no specific information to indicate that there is the likelihood of use of smallpox as a weapon in the immediate future, it does recognize that bioterrorism has become a potential health risk to America and its military forces abroad. As part of the Nation's improved preparedness against the bioterrorism threat, the Department of Defense (DoD) decided to vaccinate medical teams at its hospitals and clinics and selected other personnel against smallpox, to preserve our ability to perform critical missions. Personnel vaccinated against smallpox will be prepared to deal with the initial stages of a smallpox outbreak, if it happens. You have been asked to be vaccinated now as part of the DoD preparations against a smallpox outbreak.

Who Should Not Get Smallpox Vaccine?

In a smallpox outbreak, anyone exposed to smallpox should get the vaccine. But when it is not an emergency outbreak situation, some people should not get smallpox vaccine, including:

- People whose immune system is not working fully (e.g., due to disease, medication, or radiation). Examples: HIV/AIDS, cancer, organ transplant, immune deficiency.

- People diagnosed with eczema or atopic dermatitis, either now or at any time earlier in life.
- People with current skin conditions, such as burns, impetigo, contact dermatitis, chickenpox, shingles, psoriasis, or uncontrolled acne, until the condition clears up.
- Pregnant women.
- People with a household or other intimate contact who meets any of the conditions above.
- Breast-feeding mothers.
- Anyone who had problems after previous doses of smallpox vaccine or who is allergic to smallpox vaccine or any of its components.
- People recovering from eye surgery, such as PRK or LASIK procedures to correct vision.
- Anyone else whose physician recommends be exempt from smallpox vaccination for medical reasons.

Dosage

Smallpox vaccine is administered by jabbing the skin several times with a 2-pronged (bifurcated) needle. Usually, one vaccination (one set of jabs) is sufficient to produce an immune response. If you do not develop the expected response at your vaccination site, you will be offered a repeat vaccination. To maintain immunity, you may need another dose of smallpox vaccine. If this is your first smallpox vaccination, you would need another smallpox vaccination about 5 years from now. If you are about to get a smallpox revaccination, you would need another smallpox vaccination about 10 years from now.

What To Expect At A Smallpox Vaccination Site

If smallpox vaccination is successful, a red and itchy bump develops at the vaccination site in 2 to 4 days. Over the next few days, the bump becomes a blister and fills with pus. During the second week, the blister begins to dry up and a scab forms. The scab falls off in the third week, leaving a scar. People vaccinated for the first time may have a stronger reaction than those being revaccinated.

Anyone who does not get the expected response may need to be revaccinated. If you have a question or concern about the smallpox vaccination site, contact your primary-care manager, medical department representative, or healthcare provider.

Vaccinia virus is present on the skin at the vaccination site until the scab falls off. Be careful not to touch it, so you don't spread the virus elsewhere, especially to the eyes, nose, mouth or genitalia.

Wash your hands frequently. Alcohol-based cleansers or soap and water are both effective.

If you need medical care in the month after your vaccination, tell your provider you just got a smallpox vaccination.

How Should A Smallpox Vaccination Site Be Cared For?

Three Key Points:

1. Don't touch your vaccination site.
2. If you touch it by accident, wash your hands right away. Wash your hands frequently.
3. Don't let others touch your vaccination site or materials that touched it.

Vaccine virus (vaccinia) is present at the vaccination site for about 14 to 21 days, until the scab falls off. This means other people can get infected if they come in contact with virus from your arm. Minimize close contact with infants in household settings until the scab falls off. Or have someone else handle the infant.

Most vaccination sites can be left unbandaged, especially when not in close contact with other persons. When in close contact with others, wear sleeves covering the site. Use an absorbent bandage as a touch-resistant barrier. Dispose of bandages in sealed or double plastic bags. You may carefully add a little bleach to the bag, if desired, to kill the virus.

Keep the site dry. Airing will speed healing. Do not use creams or ointments; they will delay healing and can spread the virus. Wearing long-sleeved clothing during the day/night can protect the site. Launder clothing and linens that touch the site in hot water with soap or bleach.

Until your scab falls off, avoid close contact with people who, for medical reasons, cannot receive this vaccine. Do not share a bed, bunk, or cot with them. Do not share clothes, towels, linen, or toiletries.

Normal bathing can continue. Dry the vaccination site last, so the towel does not rub or spread virus elsewhere. Don't allow others to use that towel until laundered. Don't use public towels, unless laundry workers are alerted that you were vaccinated. Use a waterproof bandage if you exercise enough to cause sweat to drip. Avoid swimming and hot tubs. Avoid anything that rubs against the vaccination site.

Launder clothing, towels, and linens in hot water with detergent or bleach. When the scab falls off, flush it down the toilet or discard it securely in the trash. Wash your hands.

Follow these instructions carefully, or you could harm yourself or others.

What Special Precautions Should Healthcare Workers Take?

Healthcare workers should follow additional safeguards recommended by their supervisors.

Specifically, healthcare workers should follow local procedures for wearing specific bandages over the smallpox vaccination site, having these bandages checked and changed at appropriate intervals (for example, checked at the start of each duty shift, changed when the bandage collects drainage or every few days). Hospitals and clinics will assist workers who develop allergic or other reactions to bandage materials.

Healthcare workers should use one or more layers of sleeves over the bandage, as additional layer(s) of protection.

Healthcare workers should follow local infection-control procedures regarding hand washing, hygiene, change of clothing (such as scrubs or white coats), and other matters pertaining to smallpox vaccination.

Healthcare workers who work at other healthcare institutions should inform their other supervisors that they have been recently vaccinated against smallpox.

What Side Effects Are Expected After Smallpox Vaccination?

Most people have normal, usually mild, reactions after smallpox vaccination. Examples include itching, swollen lymph nodes, sore arm, fever, headache, body ache, mild rash, or fatigue. These symptoms may peak 8 to 12 days after vaccination.

In the past, about 1,000 out of every 1,000,000 vaccinated people experienced reactions that were serious, but not life-threatening. Most of these reactions involved spread of vaccine virus elsewhere on the body, especially the eye. Spread elsewhere on the body is known as “auto-inoculation” or inadvertent inoculation.

In the past, between 14 and 52 people out of 1,000,000 vaccinated for the first time experienced potentially life-threatening reactions. These reactions included serious skin reactions and inflammation of the brain (encephalitis). From past experience, 1 or 2 people in 1,000,000 who receive smallpox vaccine may die as a result.

The risks of serious reactions after smallpox vaccination, while rare, are higher than the risks associated with most other vaccines.

DoD will try to reduce the risk of side effects by actively looking for and exempting people who should not receive this vaccine.

What Treatment or Compensation is Available for Adverse Effects?

For DoD civilian employees or contractor personnel receiving smallpox vaccine under the DoD Smallpox Vaccination Program, if you believe you have an adverse reaction requiring medical attention, you should go to a military treatment facility or occupational health clinic for an initial assessment and any needed emergency care, consistent with any applicable occupational health program procedures. Your supervisor can get you additional information.

For DoD civilian employees receiving smallpox vaccine under the DoD Smallpox Vaccination Program based on employment (for example, as a healthcare worker), an adverse reaction would entitle the employee to worker's compensation coverage under the Federal Employees Compensation Act. This will cover additional medical treatment and compensation for inability to work, if any. Standard agency procedures for work-related injuries should be followed. Your supervisor can get you additional information.

For contractor personnel receiving smallpox vaccine under the DoD Smallpox Vaccination Program based on employment, worker's compensation coverage is based on the State worker's compensation program. This will determine rights and procedures concerning further medical treatment and compensation for inability to work, if any. Your employer or State worker's compensation agency can give you additional information.

Other Precautions & Warnings

If you have a mild illness at the time vaccination is scheduled, you can still take the vaccine. However, if you are moderately or severely ill, you should wait to get the vaccine. You should advise the doctor or health practitioner administering the vaccine if you are ill.

Please note that women should avoid getting pregnant for 4 weeks after smallpox vaccination.

It is especially important for people caring for infants younger than 1 year of age to take precautions recommended of all smallpox vaccine recipients.

There is no evidence that vaccinia virus from smallpox vaccine can infect cats, dogs, or other household pets, nor that pets can spread the virus to other people in the household. Take the usual protective steps (such as sleeves, bandages, hand washing) to keep the virus from reaching your pet(s).

Inform other people with a need to know that you recently received a smallpox vaccination (e.g., other employers, family members, healthcare providers who treat you).

If you become sick after smallpox vaccination, seek medical care as appropriate for the condition. Inform your healthcare provider that you recently received smallpox vaccine.

Extensive additional information is available about experience with smallpox vaccine over the last 100 years. If you would like additional information, we can provide it to you.

Monitoring for New Side Effects of Smallpox Vaccine

With more modern ways of analyzing vaccine safety, we may discover new information about side effects of smallpox vaccine. Sometimes, illness occurs after vaccination that may not or may not be caused by the vaccine. Through surveillance of large populations, previously unrecognized or rare vaccine reactions may be identified.

Please report any medical problems after any vaccination to your healthcare provider, so they can be reported to the Vaccine Adverse Event Reporting System (VAERS). VAERS is operated by the FDA and the Centers for Disease Control & Prevention (CDC). We encourage you to work with your healthcare provider in completing reports to VAERS. You may also directly report these events to VAERS yourself. You can submit VAERS reports on-line at www.vaers.org or call 800.822.7967.

Vaccination is Voluntary

For civilian personnel not subject to mandatory immunization, the decision to receive smallpox vaccination is completely voluntary. You may decline the vaccination with no adverse consequences or loss of any rights and benefits. If you have questions, please contact your local healthcare provider, your supervisor, or the Commander of the unit to which you are assigned.

Please keep these pages for your records.

Please sign the Vaccine Administration Consent on the following page.

Please return the signed page to the healthcare provider who administers the vaccine to you.

CONSENT TO RECEIVE SMALLPOX VACCINE

I have read or have had explained to me the information about smallpox and smallpox vaccine on pages 1 through 6 of this document. I understand:

- The benefits and risks of smallpox vaccination.
- The conditions (including pregnancy or possible pregnancy) that would exclude me from receiving smallpox vaccination.
- What to expect at the smallpox vaccination site.
- How the vaccination site should be cared for.
- The expected side effects from smallpox vaccination.
- Smallpox vaccination is voluntary for me.

I consent to receiving smallpox vaccination.

Signature of person _____
receiving vaccination:

Date: _____

Information about the person receiving the vaccination. (Please print.)

Last Name _____ First _____ Middle _____

Birth date _____ (mm/dd/yyyy).

Social Security Number _____

Street _____ City _____ State _____

Zip or Postal Code _____ Country _____

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Clinic/Health Unit Information. (Please Print.)

Clinic Name _____

Street _____ City _____ State _____

Postal Code _____ Country _____ Vaccination Date _____

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PRIVACY ACT STATEMENT:

AUTHORITY: Sections 113, 3013, 5013, and 8015 of Title 10, United States Code and Executive Order 9397.

PRINCIPAL PURPOSE: To document your understanding of important information about smallpox and smallpox vaccine and that you voluntarily consent to receiving it.

ROUTINE USES: None.

DISCLOSURE: Voluntary, but failure to do so may prevent the Department of Defense from giving you the smallpox vaccination.